(c) whether it is a fact that closing down of the above units will hamper the vaccination programmes;

(d) if so, how the Ministry is planning to go ahead with the vaccination programme;

(e) whether stoppage of vaccine production by above units will lead to price hike or shortage of vaccines in the country; and

(f) if so, what plan the Ministry has in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) No Sir, The manufacturing licenses of the three Government vaccine units were suspended in January 2008 because of non-compliance of Good Manufacturing Practice.

(c) and (d) No Sir, it is proposed to procure vaccines required for immunization programme from the other manufactures in Public and Private Sector in the country for distribution. The private vaccine manufactures have enough capacity in the country to cater to the requirement of Immunization Programme.

(e) and (f) No Sir, Prices for vaccines are being finalized on the basis of competitive bidding and lowest basis. However, under the immunization programme vaccines are made available to the public from the Government outlets free of cost and as per the current status and the shortage of vaccine is not expected in the country.

Clinical trials in the country

†844. SHRIMATI SUSHMA SWARAJ: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that 139 clinical trials were conducted in the year 2007 in India;

(b) if so, repercussions thereof which have come to the fore; and

(c) the parameters set for selection of foreign drugs for clinical trial in India?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) In the year 2007, the Drugs Controller General (India) has permitted 273 global clinical trials. However, actual number of clinical trials conducted in 2007 in the country is not known, as registration of clinical trials is currently not mandatory.

Recently deaths of 49 children in 42 clinical studies in AIIMS, New Delhi have come to the fore. 6 out of the 42 trials conducted, were funded by pharmaceutical companies and permission for these studies were obtained from DCG(I). There were no deaths in any of these trials.

The Director, AIIMS, New Delhi had constituted a committee to examine the issue of media reports regarding deaths among children in clinical trials. The key finding of the report shows that all studies had scientific rationale and had undergone necessary scientific review. All the study protocols were approved by, the Ethics Committee of AIIMS. None of the deaths reported during clinical studies could be attributed to treatment modality under trial and they were due to the underlying high risk illnesses and serious co-morbid disease conditions that the children suffered from.

†Original notice of the question was received in Hindi.

(c) Schedule – Y (amended in 2005) of Drugs and Cosmetics Rules, 1945 specifies the guidelines and requirements for conducting clinical trial in the country. This is applicable for both foreign drugs as well as domestic drugs for clinical trial in India. As per the said Schedule, it is also mandatory to conduct clinical trial as per Good Clinical Practice (GCP) guidelines (2001) published by Government of India. Application for clinical trial is required to be submitted in Form-44 along with prescribed fees and chemical and pharmaceutical information, animal and pharmacological, toxicological data, human clinical data of safety and efficacy etc.

Cervical cancer cases

845. SHRIMATI T. RATNA BAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that large number of women are suffering from cervical cancer in the country;

(b) if so, the details thereof and the steps taken so far to contain the same especially in Andhra Pradesh;

(c) whether the tests have become more accurate to confirm the same;

(d) if so, the details thereof;

(e) whether pilot programmes are to be launched in the country aimed at rapid and accurate results having minimal need of infrastructure; and

(f) if so, details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) As per the data collected from Population Based Cancer Registries Programme functioning under the National Cancer Registry Programme of Indian Council of Medical Research (ICMR), the age adjusted incidence rate of cervical cancer in India is between 1.8 to 22.5 per 1 lakh women. The ICMR has already initiated a project in the States of Andhra Pradesh and Gujarat to understand the suitable strategies through existing health infrastructure.

(c) to (f) The screening programmes involve Cytology, Visual inspection and HPV testing. ICMR and International Agency for Research and Cancer (WHO), Lyon, France has conducted research for evaluating the test characteristics of these three modalities of screening. These screening modalities have sufficient sensitivity and specificity (accuracy) to be used as screening tools.

Infant deaths after vaccination

846. SHRIMATI T. RATNA BAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether cases of infant deaths after vaccination have been reported recently;

(b) if so, the details thereof and the reasons therefor; and

(c) the steps to be taken to protect each and every child at the time of vaccination?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Yes Sir, four deaths of infant were reported following